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10/783,983	02/20/2004	Jessamine Lee	H0498.70190US00	4383
7590 Timothy J. Oyer, Ph.D. Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			EXAMINER BOYER, RANDY	
			ART UNIT 1797	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/783,983

**Applicant(s)**

LEE ET AL.

**Examiner**

RANDY BOYER

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) 37-52, 66-76, 78-82 and 86-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36, 53-65, 77 and 83-85 is/are rejected.
- 7) ☒ Claim(s) 10 and 64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6 October 2004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-36, 53-64, 83, and 84) in the reply filed on 10 November 2008 is acknowledged. The traversal is on the ground(s) that a single search and examination covering all claims would not place undue burden on the Examiner. This is not found persuasive because more than a "single" search would be required for proper examination of all the claims, as explained in detail with the previous Office Action mailed 15 October 2008.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 66-76, 78-82, and 86-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10 November 2008.

### ***Claim Objections***

3. Claim 10 is objected to for lack of antecedent basis in the claim.

4. With respect to claim 10, the claim recites the limitation "the inhibitor." There is insufficient antecedent basis for such limitation in the claim. Appropriate correction is required.
5. Claim 64 is objected to for improper use of the English language.
6. With respect to claim 64, the phrase "comprising a second plurality to interaction materials" should be changed to "comprising a second plurality of interaction materials" (emphasis added). Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4, 5, 15-17, 29, 30, 33-36, 83, and 84 are rejected under 35 U.S.C. 102(e) as being anticipated by Kopf-Sill (US 6,858,185).
9. With respect to claims 1, 2, 4, and 5, Kopf-Sill discloses a microfluidic system (see Kopf-Sill, Fig. 5) comprising: (a) a first fluid path (504); (b) a second fluid path (510) segregated from the first fluid path (504) by a first convection controller (508) at a first contact region; wherein at least one of the first fluid path (504) and the second fluid path

(510) has a cross-sectional dimension of less than about 1 mm (see Kopf-Sill, column 5, lines 19-20); wherein the first fluid path (504) and the second fluid path (510) are substantially tangentially intersecting at the first contact region (e.g., with a crossing angle of about 90 degrees) (see Kopf-Sill, Fig. 5).

10. With respect to claims 15-17, Kopf-Sill discloses wherein an interaction material (e.g., sample reagent) is positioned within one of the first fluid path and second fluid path (see Kopf-Sill, column 10, lines 13-39); and wherein the interaction material may be immobilized within the one of the first fluid path and the second fluid path (see Kopf-Sill, column 23, lines 18-30).

11. With respect to claim 29, Kopf-Sill discloses a fluidic array comprising: (a) a first set of fluid paths (e.g., vertical lines intersecting reservoirs (516, 518, 520, 522) with the main flow channel (504)) arranged generally parallel to one another; (b) a second set of fluid paths (504, 508) arranged generally parallel to one another and crossing the first set of fluid paths such that a plurality of contact regions are formed between at least some of the fluid paths in the first set of fluid paths and at least some of the fluid paths in the second set of fluid paths; and (c) a convection controller (510) segregating one of the first set of fluid paths from one of the second set of fluid paths at the contact region.

12. With respect to claim 30, Kopf-Sill discloses a method of promoting interaction comprising: (a) introducing a first fluid including a first material into a first fluid path (504) having a cross-sectional dimension of less than 1 mm; (b) introducing a second fluid including a second material into a second fluid path (510) segregated from the first fluid path by a convection controller (508) at a contact region; and (c) allowing the first and

second materials to interact at the contact region (see Kopf-Sill, column 6, lines 65-67; and column 7, lines 1-11).

13. With respect to claims 33-36, Kopf-Sill discloses flowing at least one of the first fluid through the first fluid path and the second fluid through the second fluid path (see Kopf-Sill, column 12, lines 18-42); wherein one of the first fluid or the second fluid may be immobilized in the respective fluid paths (see Kopf-Sill, column 16, lines 36-52; and column 23, lines 11-30).

14. With respect to claims 83 and 84, Martin discloses an apparatus comprising: (a) at least first, second, and third fluid paths (paths connecting reservoirs (502, 516, and 518) with the main flow channel (504), respectively) each having an inlet end and a region downstream from the inlet end (see Kopf-Sill, Fig. 5); the inlet of the first fluid path being fluidly connectable to a first source of fluid; the inlets of the second and third fluid paths connectable to a second source of fluid (see Kopf-Sill, column 12, lines 18-42); (b) a first connecting path (504) fluidly connecting the first fluid path and the second fluid path downstream of the inlet end of each (see Kopf-Sill, Fig. 5); and (c) a second fluid path (506, 508) fluidly connecting the second fluid path and the third fluid path downstream of the inlet end of each, and downstream of the connection of the second fluid path to the first connecting path; wherein the third fluid path is not connected to any other fluid path between its inlet and its connection to the second connecting fluid path (see Kopf-Sill, Fig. 5).

15. Claims 1, 3, 6, 7, 13, 27, 53, and 54 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Martin (US 6,129,973).

16. With respect to claims 1, 3, 6, 7, and 13, Martin discloses a microfluidic system comprising: (a) a first fluid path (1310); (b) a second fluid path (1312) segregated from the first fluid path (1310) by a first convection controller (1300) at a first contact region; wherein at least one of the first fluid path (1310) and the second fluid path (1312) has a cross-sectional dimension of less than about 1mm (see Martin, column 4, lines 49-52); wherein at least one of the first fluid path (1310) and the second fluid path (1312) is substantially rectangular in cross-section at the first contact region (see Martin, Fig. 6); wherein the convection controller is permeable by diffusion (see Martin, column 5, lines 14-24); wherein the convection controller has an affinity for at least one material to be used within the microfluidic system and repulses at least one material to be used within the microfluidic system (see Martin, column 7, lines 1-8); and wherein the convection controller comprises a membrane (see Martin, column 6, lines 20-38).

17. With respect to claim 27, Martin discloses wherein both the first fluid path and the second fluid path have a cross-sectional area of less than about 500  $\mu\text{m}$  (see Martin, column 4, lines 48-52).

18. With respect to claims 53 and 54, Martin discloses a fluidic device comprising: (a) a substrate (1300) with a material patterned thereon (see Martin, column 8, lines 1-17); and (b) a first fluid path (1312, 1314) in fluid contact with the substrate (1300) such that the fluid path (1312, 1314) is in fluid contact with at least a portion of the material (see Martin, column 7, lines 15-33).

***Claim Rejections - 35 USC § 102 / 35 USC § 103***

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



22. Claims 1, 3, 6-9, 11-21, 27, 53, 54, 62, and 63 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hediger (S. Hediger et al., *Biosystem for the Culture and Characterization of Epithelial Cell Tissues*, 63 SENSORS AND ACTUATORS B 63-73 (2000)). Alternatively, claims 1, 3, 6-9, 11-21, 27, 53, 54, 62, and 63 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hediger (S. Hediger et al., *Biosystem for the Culture and Characterization of Epithelial Cell Tissues*, 63 SENSORS AND ACTUATORS B 63-73 (2000)), as evidenced by Beattie (J.K. Beattie, *The Intrinsic Charge on Hydrophobic Microfluidic Substrates*, 6 LAB CHIP 1409-1411 (2006)).

23. With respect to claims 1, 6, 7, 9, and 27, Hediger discloses a microfluidic system comprising: (a) a first fluid path (top reservoir); (b) a second fluid path (bottom reservoir) segregated from the first fluid path by a first convection controller (polycarbonate membrane) at a first contact region; wherein at least one of the first fluid path and the second fluid path has a cross-sectional dimension of less than about 1 mm (see Hediger, Fig. 1); wherein the convection controller is permeable by diffusion (see Hediger, page 65); wherein the convection controller has an affinity for at least one material to be used within the microfluidic system and repulses at least one material to be used within the microfluidic system (see Hediger, Fig. 1 and accompanying text); wherein the convection controller comprises pores about 0.05 to 0.2 microns in diameter (see Hediger, Fig. 1); and wherein both the first and second fluid paths have a cross-sectional dimension of less than about 500  $\mu\text{m}$  (see Hediger, Fig. 1).

24. With respect to claim 8, Hediger discloses wherein the convection controller is a polycarbonate membrane (see Hediger, Fig. 1 and accompanying text) which is known to be inherently charged (see e.g., Beattie, page 1409).

25. With respect to claims 11-14, Hediger discloses wherein the convection controller is a polycarbonate membrane that is 10 microns thick (see Hediger, Fig. 1).

26. With respect to claims 15-17, Hediger discloses wherein the microfluidic system may comprise a test fluid (physiological medium) (see Hediger, Fig. 1); and wherein the test fluid may be immobilized within the first or second fluid path (see Hediger, entire disclosure).

27. With respect to claims 53 and 54, Hediger discloses a fluidic device comprising: (a) a substrate with a material patterned thereon; and (b) a first fluid path in fluid contact with the substrate such that the fluid path is in fluid contact with at least a portion of the material; wherein the material is patterned onto the substrate in at least one strip (see Hediger, Figs. 1 and 3 with accompanying text).

28. With respect to claims 62 and 63, Hediger discloses (or otherwise suggests) a method of promoting interaction comprising: (a) providing a fluidic system comprising a fluid path having a cross-sectional dimension of less than one millimeter and a first interaction material patterned therein (see Hediger, Fig. 1 and accompanying text; and page 65); (b) flowing a fluid comprising a second interaction material into the fluid path to allow interaction between the first and second interaction materials (see Hediger, page 69); and observing the interaction of the first and second interaction materials (see Hediger, pages 69-72).

29. Claims 1, 3, 6, 7, 13, 15-17, 53, and 54 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gao (J. Gao et al., *Integrated Microfluidic System Enabling Protein Digestion, Peptide Separation and Protein Identification*, 73 ANAL. CHEM. 2648-2655 (2001)).

30. With respect to claims 1, 3, 6, 7, 13, and 15-17, Gao discloses (or otherwise suggests) a microfluidic system comprising: (a) a first fluid path (upper microchannel) (see Gao, Figure 2); (b) a second fluid path (lower microchannel) segregated from the first fluid path by a first convection controller (PVDF membrane) at a first contact region (see Gao, Figure 2); wherein at least one of the first fluid path and the second fluid path has a cross-sectional dimension of less than about 1 mm (i.e. wherein the channels are "micro" channels) (see Gao, entire disclosure); wherein at least one of the first fluid path and the second fluid path is substantially rectangular in cross-section at the first contact region (see Gao, Figure 2 and accompanying text); wherein the convection controller is permeable by diffusion (see Gao, pages 2650-2655); wherein the convection controller has an affinity for at least one material to be used within the microfluidic system and repulses at least one material to be used within the microfluidic system (see Gao, pages 2650-2655); wherein the convection controller comprises a membrane (see Gao, Figure 2 and accompanying text); wherein a test fluid is positioned within one of the first or second fluid paths (see Gao, pages 2650-2655); and wherein the interaction material may be immobilized within one of the first and second fluid paths (see Gao, pages 2650-2655).

31. With respect to claims 53 and 54, Gao discloses (or otherwise suggests) a fluidic device comprising: (a) a substrate with a material patterned thereon (see Gao, Figure 2 and accompanying text); and (b) a first fluid path in contact in fluid contact with the substrate such that the fluid path is in contact with at least a portion of the material; and wherein the material is patterned onto the substrate in at least one strip (see Gao, Figure 2 and accompanying text; and page 2655).

32. Claims 53-64 and 77 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kopf-Sill (US 6,858,185).

33. With respect to claims 53-61, Kopf-Sill discloses (or otherwise suggests) a fluidic device comprising: (a) a substrate with a material patterned thereon (see Kopf-Sill, Fig. 5 and accompanying text); and (b) a first fluid path in fluid contact with the substrate such that the fluid path is in fluid contact with at least a portion of the material (see Kopf-Sill, Fig. 5 and accompanying text); wherein the material is patterned onto the substrate in at least one strip or a plurality of strips that are substantially linear, substantially parallel, and substantially perpendicular to the portions of the plurality of fluid paths that are substantially linear and parallel (see Kopf-Sill, Fig. 5 and accompanying text).

34. With respect to claims 62-64, Kopf-Sill discloses (or otherwise suggests) a method of promoting interaction comprising: (a) providing a fluidic system comprising a fluid path having a cross-section dimension of less than one millimeter and a first interaction material patterned therein (see Kopf-Sill, Fig. 5 and accompanying text; column 5, lines 19-20; column 16, lines 36-46; and column 23, lines 11-30); and (b) flowing a fluid comprising a second interaction material into the fluid path to allow

interaction between the first and second interaction materials (see Kopf-Sill, column 23, lines 11-30); observing the interaction of the first and second interaction materials (see Kopf-Sill, column 28, lines 6-20); wherein providing further comprises providing a fluidic system comprising a plurality of fluid paths and a first plurality of interaction materials patterned within them and wherein flowing further comprises flowing a plurality of fluids comprising a second plurality of interaction materials into the plurality of fluid paths (see Kopf-Sill, Fig. 5 and accompanying text; and column 23, lines 11-30).

35. With respect to claim 77, Kopf-Sill discloses the use of multiple sensors (detectors) (532, 632, 634, 636, 638) in the various fluid paths (see Kopf-Sill, Figs. 5 and 6 with accompanying text).

### ***Claim Rejections - 35 USC § 103***

36. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

37. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

38. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

39. Claims 1, 2, 4, 5, 10, 22-26, 28, 29, 53-65, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hediger (S. Hediger et al., *Biosystem for the Culture and Characterization of Epithelial Cell Tissues*, 63 SENSORS AND ACTUATORS B 63-73 (2000)).

40. With respect to claims 1, 2, 4, and 5, see discussion *supra* at paragraph 23.

Hediger does not explicitly disclose wherein the first fluid path and the second fluid path are substantially tangentially intersecting at the first contact region; wherein the first fluid and the second fluid path have a crossing angle between about 45 and 135 degrees; or wherein the first fluid path and the second fluid path have a crossing angle of about 90 degrees.

However, the mere rearrangement of parts of a prior art device is not sufficient to establish patentability over the prior art. See MPEP § 2144.04(VI)(C).

Therefore, Examiner finds Applicant's claims 1, 2, 4, and 5 unpatentable over the disclosure of Hediger.

41. With respect to claim 10, Hediger discloses wherein the membrane pores are about 0.4  $\mu\text{m}$  in diameter (see Hediger, Fig. 1). Moreover, mere changes in size are generally insufficient to establish patentability over the prior art in the absence of new or unexpected results. See MPEP § 2144.04(IV)(A).

42. With respect to claims 22-26, 28, and 29, the mere duplication of parts is generally insufficient to establish patentability over the prior art in the absence of new or unexpected results. See MPEP § 2144.04(VI)(B).

43. With respect to claims 53-65 and 85, see discussion *supra* at paragraphs 27 and 28.

Examiner notes that the mere duplication and/or rearrangement of parts of a prior art device is generally not sufficient to establish patentability over the prior art in the absence of new or unexpected results. See MPEP §§ 2144.04(VI)(B)-(C).

44. Claims 1, 2, 4, 5, 6, 9-12, 18-36, 53-65, 77, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao (J. Gao et al., *Integrated Microfluidic System Enabling Protein Digestion, Peptide Separation and Protein Identification*, 73 ANAL. CHEM. 2648-2655 (2001)).

45. With respect to claims 1, 2, 4, 5, 6, 9-12, 18-36, 53-65, and 85, see discussion *supra* at paragraphs 30 and 31.

Examiner notes that the mere duplication and/or rearrangement of parts of a prior art device as well as mere changes in size of a prior art device are generally not

sufficient to establish patentability over the prior art in the absence of new or unexpected results. See MPEP §§ 2144.04(IV)(A) and 2144.04(VI)(B)-(C).

46. With respect to claim 77, Gao discloses use of electrospray ionization mass spectrometry to analyze the product streams of the microfluidic system (see Gao, page 2648).

47. Claims 1, 3, 22, 24-28, 30, 31, 65, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopf-Sill (US 6,858,185).

48. With respect to claims 1, 3, 22, 24-28, 30, 31, 65, and 85, see discussion *supra* at paragraphs 9-14.

Examiner notes that the mere duplication and/or rearrangement of parts of a prior art device as well as mere changes in size of a prior art device are generally not sufficient to establish patentability over the prior art in the absence of new or unexpected results. See MPEP §§ 2144.04(IV)(A) and 2144.04(VI)(B)-(C).

49. With respect to claim 31, Kopf-Sill discloses wherein all fluid paths are exposed to the same source of pressure for control of the device (see Kopf-Sill, column 6, lines 31-43).

50. Claims 1, 2, 4, 5, 9-12, 14-17, 30-36, 53-65, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 6,129,973). Alternatively, claims 1, 2, 4, 5, 9-12, 14-17, 30-36, 53-65, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 6,129,973), as evidenced by Hediger ((S. Hediger et al., *Biosystem for the Culture and Characterization of Epithelial Cell Tissues*, 63 SENSORS AND ACTUATORS B 63-73 (2000)).



51. With respect to claims 1, 2, 4, 5, 9-12, 14, 53-65, and 85, see discussion *supra* at paragraphs 16-18.

Examiner notes that the mere duplication and/or rearrangement of parts of a prior art device as well as mere changes in size of a prior art device are generally not sufficient to establish patentability over the prior art in the absence of new or unexpected results. See MPEP §§ 2144.04(IV)(A) and 2144.04(VI)(B)-(C). Furthermore, Martin discloses wherein the membrane may comprise polymer material (see Martin, column 8, lines 18-34). In this regard, Examiner notes that polycarbonate membranes are known in the art for use in microfluidic systems (see e.g., Hediger, Fig. 1).

52. With respect to claims 15-17, Martin discloses wherein a test fluid may be positioned in one of the first or second fluid paths (see Martin, column 7, lines 15-33) or else immobilized in the microfluidic device (see Martin, column 5, lines 13-33).

53. With respect to claims 30-36, Martin discloses (or otherwise suggests) a method of promoting interaction comprising: (a) introducing a first fluid including a first material into a fluid path having a cross-sectional dimension of less than 1 mm (see Martin, Fig. 6 and accompanying text); (b) introducing a second fluid including a second material into a second fluid path segregated from the first fluid path by a convection controller (microporous contactor sheet) at a contact region (see Martin, Fig. 6 and accompanying text); and (c) allowing the first and second materials to interact at the contact region (see Martin, column 7, lines 15-33); maintaining a pressure within the first fluid path at the contact region substantially equal to a pressure with the second fluid path at the

contact region (see Martin, column 6, lines 41-45); diffusing at least the first or second material into the convection controller (see Martin, column 5, lines 13-33); flowing at least the first or second fluid through the second fluid path (see Martin, column 7, lines 15-33); and immobilizing at least one of the first or second fluid in the first or second fluid paths (see Martin, column 7, lines 15-33).

### ***Conclusion***

54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randy Boyer whose telephone number is (571) 272-7113. The examiner can normally be reached Monday through Friday from 10:00 A.M. to 7:00 P.M. (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola, can be reached at (571) 272-1444. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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/Glenn A Caldarola/

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